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Douglas Hauck

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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ABBOTT LABORATORIES, et al.,

15 Civ. 5826 (CBA-MDG)

Plaintiffs,

- against -

ADELPHIA SUPPLY USA., et al.,

Defendants.
----------X

DEFENDANTS SAVE RITE MEDICAL.COM LLC'S, MARC KAPLAN'S, MATRIX DISTRIBUTORS, INC.'S, CHRISTOPHER BENEVENT'S, SETH GRUMET'S, DREAM CEREAL INC.'S AND DOUGLAS HAUCK'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

Defendants Save Rite Medical.com LLC ("Save Rite") and Marc Kaplan ("Kaplan") (collectively "Save Rite Defendants"), Matrix Distributors, Inc. ("Matrix"), Christopher Benevent ("Benevent") and Seth Grumet ("Grumet") (collectively "Matrix Defendants"), Dream Cereal Inc. d/b/a Diabetessupplies4less.com ("Dream Cereal") and Douglas Hauck ("Hauck") (collectively "Dream Cereal Defendants"), respectfully submit this Memorandum of Law in Opposition to Plaintiffs' Motion for Preliminary Injunction ("MOL").

STATEMENT OF FACTS

For the sake of brevity, the facts will be integrated into the legal subsections, *infra.*

ARGUMENT

SINCE PLAINTIFFS WILL BE UNABLE TO SHOW THAT THEY WILL SUFFER IRREPARABLE HARM , THEIR MOTION FOR A PRELIMINARY INJUNCTION SHOULD BE DENIED

Background

On October 9, 2015, Plaintiffs ("Abbott"), filed this action together with an Order To Show Cause ("OTSC"), which sought a temporary restraining order ("TRO"), a preliminary injunction ("PI"), and expedited discovery. The Complaint which is an exhibit to Abbott's application, contains Lanham Act claims and Civil RICO claims. The alleged Lanham Act violations are based upon the importation and sale of Abbott's "Freestyle" blood glucose test strips of foreign manufacture, which it is claimed infringe Abbott's trademark rights, because the product and the packaging are materially different from what Abbott sells in the United States. The Civil RICO counts are based upon an alleged conspiracy or agreement involving all the named Defendants, to engage in mail fraud and wire fraud, which the Save Rite, Matrix and

Dream Cereal Defendants will deny in their Answer. The PI application however pertains solely to the Lanham Act claims.

Judge Irizarry granted the TRO and expedited discovery Plaintiffs sought. On October 19, 2015, this Court modified the expedited discovery contained in the OTSC, set a new briefing schedule and set the motion down for an evidentiary hearing on November 4, 2015. On October 22, 2015, this Court granted H&H Wholesale Services, Inc. Howard Goldman and Lori Goldman (collectively "H&H Defendants"), the right to depose two of Abbott's Declarants, prior to the hearing. The purpose of this MOL is to address the issues the Save Rite, Matrix and Dream Cereal Defendants will raise at the hearing, in aid of establishing that Abbott is not entitled to preliminary injunctive relief.

The Law

Injunctive relief is an extraordinary remedy that may only be rewarded upon a clear showing that the plaintiff is entitled to this relief. *Winter v. National Resources Defense Council, Inc.,* 555 U.S. 7, 22 (2008). In this Circuit a party seeking a PI must demonstrate that (1) it will suffer irreparable harm in the absence of this relief; (2) either that it likely to succeed on the merits or that there are sufficiently serious questions going to the merits to make them a fair ground for litigation; and (3) the balance of hardships tips decidedly in favor of the moving party. *Mullins v. City of New York,* 626 F.3d 47, 52-53 (2d Cir. 2010); *BRDN v. United Healthcare of New York, Inc.,* 2015 WL 1841210 at *3 (SDNY 2015).

The single most important prerequisite for the issuance of a PI is a demonstration that if it is not granted, the movant will suffer irreparable harm. *Faively Transp. Malmo AB v. Wabtec Corp.,* 559 F.3d 110, 118 (2d Cir. 2009); *Citibank, N.A. v. Citytrust, 756 F.2d 273, 275* (2d Cir.

1985); *Gidatex, S.R.L. v. Campaniello Imports, Ltd.,* 13 F.Supp.2d 417, 419 (SDNY 1998). A movant's failure to establish irreparable harm is alone sufficient for a court to deny injunctive relief. *Life Technologies Corp. V. AB Sciex PTE. LTD.,* 2011WL 1419612 at *8 (SDNY 2011); *Ayco Co. v. Feldman,* 2010 WL 4286154 at *5 (NDNY 2010).

Prior to 2010, the Courts in this Circuit had held that irreparable harm may be presumed when a plaintiff establishes a prima facie case of trademark infringement. See, e.g. *Two Kids From Queens v. J&S Kidswear, Inc.,* 2009 WL 5214497 at *3 (EDNY 2009). However, in *Salinger v. Colting,* 607 F.3d 68, 79-80 (2d Cir. 2010), the Court ruled that a movant is not entitled to any presumption of irreparable harm arising from a demonstration of likelihood of success on the merits with respect to likelihood of confusion. *Accord: Vox Amplification LTD. v. Meussdorfer,* 2104 WL 558866 at * 5 (EDNY 2014); *Grout Shield Distributors, LLC v. Elio E. Salvo, Inc.,*824 F. Supp.2d 389,403 (EDNY 2011).

Rather, to establish irreparable harm in a trademark case the party seeking the injunction must show that it will lose control over the reputation of its trademark pending trial, because loss of control over one's reputation is neither calculable nor precisely compensable. *Vox Amplification, supra* at *4; *Power Test Petroleum Distributors, Inc. v. Calcu. Gas, Inc.,* 754 F.2d 91, 95 (2d Cir. 1985). Further, the movant must show not only that irreparable injury is possible, but that it is likely. *Stokely-Van Camp, Inc. v. Coca-Cola Company,* 646 F.Supp.2d 510, 531-532 (SDNY 2009); *Marcy Playground, Inc. v. Capital Records, Inc.,* 6 F.Supp.2d 277, 282 (SDNY 1998). In this regard, Courts have found that an inverse relationship exists between irreparable harm and delay in seeking this relief, with respect to likelihood of irreparable harm.

Thus delay in seeking a preliminary injunction can negate a claim of irreparable harm

because the failure to act sooner undercuts the sense of urgency that ordinarily accompanies a motion for preliminary relief and suggests that there is, in fact, no irreparable injury. *Tough Traveler, Ltd. V. Outbound Prods.,* 60 F.3d 964, 968 (2d Cir. 1990), *abrogated in part by Salinger, supra.* Indeed, the Second Circuit has found delays of as little as ten weeks sufficient to defeat a finding of irreparable harm, except where there is good reason for the delay. *Weight Watchers Int'l, Inc. v. Luiginos, Inc.,* 423 F.3d 137, 144 (2d Cir. 2005); *FC Online Marketing, Inc. v. Burke's Martial Arts, LLC,* 2015 WL 4162757 at *32 (SDNY 2015); *Gidatex,* supra at 419 (two months); *Life Technologies,* supra at *7 (two months).

With respect to laches, while delay may not warrant ultimately denial of a permanent injunction, it may preclude the granting of a preliminary injunction. *Tough Traveler, Ltd.,* supra at 968; *Chase Manhattan Corporation v. Northwestern Mutual Life,* 1993 WL 60602 at *4 (SDNY 1993). "Parties cannot seek relief for the erosion of their rights if such erosion arose because they sat on those rights." *Chase Manhattan,* supra at *4.

Abbott's submissions show a case of benign neglect with respect to protecting and enforcing its trademark rights. Abbott's indifference to the alleged proliferation of the international freestyle products over the last few years, belies their claim that the test strips constitute a public health hazard and/or are misbranded, a term that Abbott misuses with respect to its own international product.

The Thomas J. Kneir And Todd Nelson Declarations

Appended to the accompanying Declaration of Stanley R. Goodman dated October 26, 2015 ("Goodman Dec."), as Exhibits A and B respectively, are the Declarations of Thomas J. Kneir dated October 8, 2015 ("Kneir Dec.") and Todd Nelson dated October 6, 2015 ("Nelson

Dec."), which were submitted by Abbott in support of their OTSC. With regard to Kneir, he states that he has been the Director of Product Security since November 2004 (Kneir Dec. ¶ 3). According to Kneir, in early 2015, Abbott began to notice a dramatic growth in volume of the international test strips in the United States. Kneir decided to conduct an investigation to ascertain the distributors and retailers selling these test strips, who are the named Defendants in this lawsuit (*Id.*¶ 4). Kneir reiterates in Paragraph 5 of his Declaration that, "Recently, Abbott has observed a significant increase in diverted FreeStyle test trips in the U.S. market. Is early 2015 "recent" *vis a vis* seeking preliminary injunctive relief on October 9, 2015? Indeed, Kneir's Declaration, Paragraphs 11-35, shows that with the exception of Defendant Adelphia Supply USA, ("Adelphia"), Abbott waited to make undercover buys from the Defendants until September, 2015 and October, 2015. Further in the case of Defendants whose place of business was outside this District, Abbott had them ship the test strips to a location within this District to manufacture jurisdiction and venue.

Kneir's Declaration demonstrates that Abbott had been monitoring the flow of international FreeStyle test strips within the U.S. marketplace. How long this monitoring was going on will be explored at the hearing. In the case of Adelphia, it had begun no later than early 2014, when Abbott received information that Adelphia, the lead Defendant, was distributing U.S. FreeStyle test strips that Abbott manufactured for sale in the Middle East. Indeed, in May 2014, Kneir made an undercover buy from Adelphia. Kneir was then informed by an Adelphia salesperson, that Adelphia had more than 100 cases of this product for sale (*Id.* ¶ 6).

What did Abbott do upon discovering a wholesaler with a significant quantity of allegedly misbranded test strips? They had Kneir "promptly" notify the FDA's Office of

Criminal Investigations ("OCI") and the matter was assigned to the New York field office (pure hearsay) (*Id.* ¶7). What has OCI done to date? Apparently nothing, because the misbranded claim is bogus.

Besides reporting to the OCI, what did Abbott do to stem the tide of the international product from being imported and sold in the United States? Indeed, what did Abbott due about Adelphia? Nothing.

Kneir continues that in late 2014 and early 2015, not surprisingly, Abbott began receiving information that Adelphia was again offering the international product in the U.S. But this time, Abbott also discovered that other entities were doing the same (*Id.*¶ 8). Again, Abbott notified OCI, who continued to do nothing, thereby forcing Abbott, belatedly, to take "... the lead in investigating this influx and pursuing civil remedies." (*Id.* ¶ 9). With regard to Adelphia, on June 8, 2015, Abbott purchased 12 cartons of 50-count FreeStyle Lite test strips, intended for sale in the United Kingdom and Jamaica.

It should be apparent that Adelphia was a major distributor of the international product which according to its Complaint, Abbott classifies as misbranded and a possible health risk (Docket Entry # 1, ¶s 13-15). In fact, had Abbott made additional undercover buys from Adelphia after May, 2014 and before June, 2015, it is a reasonable assumption that Abbott would have discovered more of the international product being available. And what about the unnamed "other entities", discovered in late 2014 and early 2015? Why did Abbott wait nine months to make buys from these entities and almost a year to take legal action?

Indeed, Abbott could have instituted a legal action against Adelphia in May, 2014, sought a preliminary injunction and publicized the legal action as they are doing here. Clearly, that could

have had a deterrent effect upon others dealing in the international product by terminating distribution and sale. Taking legal action either in May, 2014 (Adelphia's suppliers and customers could have been added as Defendants) or earlier this year, could have prevented the situation described in Nelson's Declaration.

According to Nelson, he is General Manager of Abbott's U.S. Commercial Operations (Nelson Dec. ¶ 1). According to Nelson, "recently", Abbott began to see a substantial increase in the number of FreeStyle test strips diverted from abroad into the U.S. market. Further, according to Nelson, market consumption data ("MCD)") has shown the sale of more FreeStyle test strips in the U. S. than is being manufactured by Abbott in the United States, which means that a large volume of international test strips are being sold here (*Id.*¶ 8).

Nelson's claims are qualitative, not quantitative, which we maintain is deliberate. We believe that Abbott had been studying MCD for at least two years, which had shown a steady increase in consumer sales over and above the quantity manufactured for the U.S. market, rather than a sudden "spike" or surge in consumer sales as Nelson claims. We believe that Abbott's indifference has allowed this market in international test strips to develop.

Per Kneir's Declaration, Abbott waited until September, 2015 and October, 2015 to make purchases from Save Rite's, Matrix' and Dream Cereal's websites, although as the Court will hear, these Defendants had been receiving offers and purchasing the international products for far longer, going back to 2012 or 2013. The Court will hear that these Defendants did not import these FreeStyle test strips, but purchased them in the secondary marketplace. The fact that Abbott had not taken any legal action over this long period of time, led these Defendants to conclude, that these international test strips could be legally bought and sold. Indeed, not even cease and

desist letters were sent by Abbott to wholesaler and retailers that did not buy directly from Abbott, advising otherwise, another way of stemming the tide, short of taking summary legal action with respect to product which was authentic, not counterfeit.

Given these Defendants' offering for sale of the international product had been open and notorious for at least two (2) years, it is inexcusable that Abbott waited that long to seek a preliminary injunction against Save Rite, Matrix and Dream Cereal and others, if the sale of these products was truly causing Abbott irreparable harm. But there is more.

As stated in Goodman's Declaration, Paragraphs 14 and 15, since Abbott has stated trademark infringement claims based upon the substantial dissimilarity between the domestic test strips and the international test strips, Abbott could have sought to block the importation of the international test strips by applying to U.S. Customs and Border Protection ("CBP") for "Lever Rule Protection" pursuant to Part 133 of CBP regulations, which is appended to Goodman's Declaration as Exhibit 3, upon a finding that the international products were substantially dissimilar to the U. S. products. See also *Lever Brothers Co. v. United States,* 877 F.2d 101 (D.C. Cir. 1989).

Upon being granted Lever Rule Protection, CBP could detain and seize all imports of gray market FreeStyle test strips, thus making them unavailable to secondary market wholesalers and retailers. If these international products are causing Abbott irreparable harm, why has Abbott not sought Lever Rule Protection in 2014 or even earlier this year? Because it has not then and has not now suffered irreparable harm from the sale of test strips which itself manufactures. Abbott's sales figures prove the point.

According to Nelson's Declaration, Paragraph 4:

> "FreeStyle Test strips are sold virtually in every pharmacy in the United States. This amounts to over 600 million FreeStyle test strips sold each year to home-use consumers in the United States. Over the past 5 years, Abbott has sold billions of FreeStyle test strips in the United States for over $1 billion dollars in revenue."

That is mighty impressive.

Given the huge success of the U.S. FreeStyle test strips during the period of time that the international Freestyle test strips have been available, it is clear that the international test strips have not tarnished or diluted the FreeStyle trademarks, nor more importantly, have caused Abbott to lose control over the reputation of it trademarks or its U.S. test strips, which is necessary to justify the imposition of a preliminary injunction. This is not surprising since these are authentic products, the directions are in English, most users are experienced and Abbott admits that it has not had a recall or any consumer complaints regarding the international FreeStyle test strips.

Therefore, this Court should not be hoodwinked by the dire portrait Abbott seeks to paint regarding the international test strips, to justify a preliminary injunction. The alleged harm caused by the increased numbers of international test strips in the market place, is self inflicted. If these test strips, in addition to violating Abbott's trademark rights are also misbranded and pose a public health risk, how could Abbott in May, 2014, tolerate even 100 cases available for public consumption (Kneir Dec. ¶ 6), by not taking legal action against Adelphia at that time including seeking an immediate preliminary injunction. Did Abbott believe that Adelphia's was an isolated case? Patently, by Kneir's own admission, that notion was dispelled by late 2014 (*Id. ¶ 8).*

We anticipate that Abbott will argue that there is good reason for the delay, as given the

large number of offenders, Abbott needed time to launch a wide scaled investigation including an undercover buy from each Defendant, in order to bring a single, consolidated action. What Abbott wants the Court to overlook is that the growth of trade in the international test strips was not sudden as Abbott falsely represents, but was years in the making, due to Abbott's conscious disregard of the ever increasing importation and resale of the international test strips into the United States. Indeed, Abbott did not even avail itself of the simple expedient of obtaining Lever Rule Protection to stop these imports. As we quoted earlier, "Parties cannot seek relief for the erosion of their rights if such erosion arose because they sat on those rights." *Chase Manhattan, supra* at *4. Equity aids the vigilant and since a preliminary injunction is an equitable remedy, *Big Star Entertainment, Inc. v. Next Big Star Inc.*, 105 F.Supp.2d 185, 191 (SDNY 2000), it should be denied to this less than vigilant applicant.

The Misbranding Myth

To add an air of urgency to mask their indolence, Abbott offers another ground, namely, that these international products, because they are not approved for sale by the FDA, are therefore misbranded, and buying and selling them is a felony (Abbott's Complaint Docket Entry #1, ¶s 13-15). In a letter to this Court in response to one of H&H Defendants' applications, Abbott cited *American Home Products Corporation v. Johnson & Johnson,* 654 F.Supp. 568 (SDNY *1987)* in support of its claim that the public interest mandates the grant of a preliminary injunction, because the international products are misbranded medical devises. However, *American Home* was not a misbranding case, but one of false advertising under § 43(a) of the Lanham Act. There the Court held at p. 590 that there is a strong public interest in the prevention of misleading advertisements where OTC drugs are concerned. The instant case is not a false

advertising case. None of the Defendants have made any claims regarding the international products separate from the labeling which emanates from Abbott. Therefore, *American Home* is distinguishable on the facts.

While we appreciate the public interest plays a role, we assume that the FDA acts in the public interest with regard to drugs and medical devices by protecting the public from misbranded devices. Yet, although Abbott twice reported to the FDA Adelphia's possession of large quantities of the international FreeStyle products for sale, FDA has taken no remedial action against Adelphia or issued a public warning that Abbott international FreeStyle test strips constitute misbranded medical devices. Why? Because they are not.

Similarly, OCI has not launched a criminal investigation because offering these genuine Abbott products for sale, is not a crime. Patently, Abbott is not the Court, FDA, OCI or Department of Justice, nor possesses any special expertise on criminal law. Rather, Abbott is a partisan civil litigant, making desperate claims to mask its benign neglect in permitting a domestic market in international FreeStyle test strips to flourish and grow over the years.

Under *21 USC 352 (a),(4)(f) and (4)(j)*, a device is misbranded, *inter alia,* if its labeling is false or misleading, it contains inadequate instructions or warning or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. The latter requires two elements, namely a manner of use suggested in its labeling and a danger to health from the suggested manner of use. *United States v. Torrigian Laboratories, Inc.,* 577 F.Supp. 1514, 1525 (EDNY 1984). Since the labeling is Abbotts', they would be hard pressed to claim it is false or misleading. As far as manner of use, the instructions are in English and Abbott would also be hard pressed to claim that in international English speaking markets that the

suggested manner of use in the labeling and instructions present no danger to health, but in the United States they do. The fact that the FDA may require additional labeling information, does not render the international products misbranded, so long as the instructions for use and warnings, if any, are adequate.

In this regard, material differences in product labeling, should not be equated with danger to health from suggested manner of use, so as to render Abbotts' international product misbranded, within the meaning of *21 USC 352.* Patently, *15 USC 1114* and *1125(a)* do not control the determination whether a medical device is misbranded; only *21 USC 352* does.

Thus, Abbott's attempt to conflate the aforesaid Lanham Act statutes into the misbranding inquiry, should be rejected by this Court. As the H&H Defendants stated in their October 21, 2015 letter to this Court (Document 66) at page 3: "The Lanham Act exists to militate against consumer confusion and avoid any injury to a trademark owner's goodwill that such confusion might cause. It does not exist to police FDA labeling requirements." This is especially so as here where the labeling does not render the device misbranded within the meaning of *21 USC 352.* Repeatedly claiming otherwise, does not make it so.

In sum, Abbotts' unjustifiable delay in bringing this action and the fact that the international FreeStyle test strips do not sully Abbotts' reputation, dilute or tarnish its trademarks or pose a danger to the public health due to misbranding, establish that Abbott has not and will not suffer irreparable harm from the continued purchase and sale of the international Freestyle test strips.

CONCLUSION

ABBOTTS' MOTION FOR A PRELIMINARY INJUNCTION SHOULD IN ALL RESPECTS BE DENIED

Dated: Garden City, New York
October 26, 2015

GOODMAN & SAPERSTEIN

By: _____
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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been filed electronically with the U.S. District Court this 26th day of October, 2015. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. If a party is not given notice electronically through the Court's system a copy will be served by ordinary United States mail, first class postage prepaid.

/s/ Martin I. Saperstein